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May 12, 2008

Via Courier

Marshall Swindell
Product Manager 33, Antimicrobial Division
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: FMC Corporation; Application to Amend B-Cap 35 Antimicrobial Agent (EPA Reg. No. 72372-1)

Dear Mr. Swindell:

On behalf of our client, FMC Corporation, we are submitting an amendment to add directions for use for *B-Cap® 35 Antimicrobial Agent* as a non-food contact sterilant. This amendment was originally submitted on June 30, 2006, but was withdrawn by FMC after EPA raised concerns about modifications to the AOAC sporicidal testing guidelines. The efficacy studies have been re-run according to the EPA approved modifications and were successful in demonstrating that *B-Cap® 35 Antimicrobial Agent* is a sterilant when used according to label directions. The revised efficacy studies are enclosed with this amendment.

Data and information supporting this amendment include:

- Five copies of the label with proposed directions for use with one label in highlight indicating the new uses;
- Sporicidal efficacy studies conforming to the modified efficacy protocol approved by EPA. The test method was validated by two separate laboratories, as required by EPA;
- Copies of the Clarus™ Hydrogen Peroxide Vapor Generator User's Manual; and
- Copies of the of the appropriate EPA forms including data matrix, Certification with Respect to Data and Confidential Statements of Formula (CSF).

Please note that the alternate brand name, *Durox LR*, will be referenced in connection with the alternate formulation used in the Clarus™ Hydrogen Peroxide Vapor Generator. In each of the efficacy studies, *B-Cap® 35 Antimicrobial Agent* is referred to by the proposed alternate brand name, *Durox LR*. The two brand names refer to the same 35% hydrogen peroxide product.

Clarus™ Hydrogen Peroxide Vapor Generator

The sterilant efficacy studies were performed using *B-Cap® 35 Antimicrobial Agent* and the Clarus™ Hydrogen Peroxide Vapor Generator. As described in more detail in the user's manual, the generator is a small, mobile unit developed by Bioquell, a company in Hampsire, UK. The Clarus™ Hydrogen peroxide vapor generator has been designed and manufactured specifically for use to decontaminate small scale laboratory equipment, including biological safety cabinets, CO_2 incubators, small lyophilizers, and small containment units used for aseptic processing or biomedical containment. Other small pieces of laboratory equipment that become contaminated with microorganisms may be treated.

The Clarus™ gas generator is a mobile unit that can be connected to suitable enclosures that have been fitted with connectors to permit introduction and removal of the hydrogen peroxide vapor. The laboratory equipment are placed inside the enclosure for decontamination. The Clarus™ gas generator operates in a closed cycle and on preset or customized programs for sterilization. Four stages of operation compose a sterilization cycle. First is a "Conditioning" stage, to remove excess moisture and particulates from the air inside the chamber. Moisture is condensed using a refrigeration coil, filtered through a HEPA filter, then heated to 50 °C before returning to the chamber. Conditioning generally requires at least 10 minutes, but may be extended if excessive moisture or particulates are present.

Next is a brief "Pre-gassing" stage (approximately one minute) that permits time for the vapor generator to heat to operating temperatures, which is followed by the "Gassing" stage. During this stage, air is circulated from the chamber and into the vapor generator. The air is again filtered, and then introduced into a vaporizer that flash evaporates 35% hydrogen peroxide. The air and hydrogen peroxide vapor are then pumped back into the chamber, and the cycle continued until the air is saturated with hydrogen peroxide vapor, producing micro-condensation. The hydrogen peroxide vapor remains in the chamber for a minimum of 3 hours to achieve sterilization.

Finally, the "Aeration" stage removes the hydrogen peroxide vapor from the chamber. The vapor-saturated air is pumped back through the vapor generator, through a catalytic filter that decomposes the hydrogen peroxide to water vapor and oxygen. Excess water is again removed using the refrigeration coil. Aeration continues until the hydrogen peroxide vapor levels are at 1 ppm or less (UK Occupational Safe Exposure standard). Levels are monitored using an optional hydrogen peroxide monitor that can be purchased with the vapor generator, or a commercially available hand-held hydrogen peroxide monitor.

* * *

As we have identified other hydrogen peroxide registrations approved as sterilants (EPA Reg. 58779-4), we believe that this is not a new use. Accordingly, we believe that the appropriate PRIA category is A570 with a four-month review time and an associated fee of $3,150. We trust that this application is complete. Please do not hesitate to contact me if any questions arise during your review.

Sincerely,

Matthew E. Talley
Pesticide Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

FMC Corporation
Peroxygens Division
1735 Market Street
Philadelphia, PA 19103

2. Regulatory Action in Support of Which this Package is Submitted

APPLICATION FOR PESTICIDE REGISTRATION AMENDMENT

B-Cap 35 Antimicrobial Agent

EPA Registration No. 72372-1

3. Transmittal Date

May 12, 2008

4. List of Submitted Studies

_____	Vol. 1:	Administrative Materials
47424901	Vol. 2	Evaluation of Bioquell Clarus® Hydrogen Peroxide Vapour Generator by Modified AOAC Sporicidal Activity Test Method 966.04
47439401	Vol. 3	Evaluation of Bioquell 'Clarus' Hydrogen Peroxide Vapour Generator Modified AOAC Sporicidal Activity Test
Admin	Vol. 4	Clarus™ Hydrogen Peroxide Vapour Generator User's Manual

Company Official: Matthew Talley _____
Name Signature

Company Name: FMC Corporation

Company Contact: LuAnn Maloney 215-299-6942
Name Phone